REMARKS/ARGUMENTS

In response to the Final Office Action mailed November 24, 2003, Applicants propose to amend their application and request reconsideration in view of the proposed amendments. In this amendment, Claims 1, 16 and 17 are proposed to be amended, Claims 10, 12, 13, 15 and 52 are proposed to be cancelled without prejudice, Claims 9, 11, 14 and 18-51 were previously cancelled without prejudice and no claims have been added so that Claims 1-8, 16 and 17 are currently pending. No new matter has been introduced.

Claims 1-8 and 10 were rejected as being anticipated by U.S. Patent Application Publication Number 2002/0041899 to Chudzik et al. (Chudzik). This rejection is respectfully traversed.

Chudzik discloses a coating composition for use in delivering a medicament from the surface of a medical device positioned *in vivo*. Medicaments include a wide range of biologically active materials or drugs. A wide range of drugs and/or agents are set forth in the disclosure. Medical devices include a wide range of implantable and removable devices such as vascular stents and grafts. The medicament is typically incorporated into a polymeric matrix after the matrix itself has been coated onto a medical device. Essentially, the medical device is soaked in a medicament solution wherein it is absorbed into the matrix and the device is air dried. In certain embodiments, another polymer layer comprising the same or different polymer than that of the base layer can be affixed to the device. The medicament layer can pass through this topcoat. This method of using the second polymer layer allows for a more lubricious device according to the disclosure.

The present invention, as claimed in amended independent Claim 1, is directed to a local drug delivery device which comprises a medical device for implantation into a treatment site of a living organism, a layer including at least one agent in therapeutic dosages incorporated in a polymeric matrix and affixed to the medical device for the treatment of reaction by the living organism caused by the medical device or the implantation thereof, and a water soluble powder

for preventing the at least one agent from separating from the medical device prior to implantation. The water-soluble powder being affixed to the layer affixed to the medical device.

Anticipation exists only if all of the elements of the claimed invention are present in a system or method disclosed, expressly or inherently, in a single prior art reference. Therefore, if it can be shown that there is one difference between the claimed invention and what is disclosed in the single reference, there can be no anticipation.

Chudzik fails to disclose a water-soluble powder affixed to a layer comprising a polymer and a therapeutic dose of an agent. Since there is at least this one difference, there can be no anticipation. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 12 and 13 were rejected as being unpatentable over Chudzik in view of U.S. Patent Number 6,306,144 to Sydney et al. (Sydney) or U.S. Patent Number 5,272,012 to Opolski (Opolski). Claims 12 and 13 were cancelled without prejudice; accordingly, the rejection is now moot.

Claims 15-17 and 52 were rejected as being unpatentable over Chudzik. This rejection is respectfully traversed.

Claims 15 and 52 have been cancelled without prejudice; accordingly, the rejection of these claims is now moot.

Claims 16 and 17 depend from Claim 1 and thus the remarks will be so directed.

The MPEP, in section 706.02(j), sets forth the basic criteria that must be met in order to establish a *prima facie* case of obviousness.

> "To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation,

> either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In re Vaeck, 947 F.2d,488,20 USPQ2d 1438 (Fed.Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria."

Section 2143.03 of the MPEP clarifies certain criteria in section 706.02(j).

> "To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1074). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)."

It is respectfully submitted that Chudzik fails to disclose a water-soluble powder affixed to the polymeric coating comprising a therapeutic dosage of an agent for treating certain reactions. What Chudzik discloses is a method for creating a lubricious coating onto a drug/polymer matrix as set forth in paragraph 0080 of Chudzik. The method involves the use of the same or different polymer, in solution form, to be affixed to the device and basecoat. Chudzik only discusses polymers for adding lubriciousness. Chudzik fails to disclose or even remotely

suggest the use of a water-soluble powder that potentially makes a polymer less "sticky." Therefore, since Chudzik fails to suggest all of the claimed elements, there is no *prima facie* obviousness. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1-8, 10, 12, 13, 15-17 and 52 were rejected as being unpatentable over Chudzik in view of Sydney or Opolski. This rejection is respectfully traversed.

Claims 10, 12, 13, 15 and 52 were cancelled without prejudice and thus any rejection thereof is now moot.

Opolski discloses a medical apparatus having a protective, lubricious coating. More specifically, Opolski discloses a coating solution that includes a slip additive for creating a reduced friction surface and a protective compound. The coating solution may also comprise therapeutic agents. The coating may be affixed to the apparatus in any number of ways. The coating described is flexible, durable and lubricious. All coatings are solutions with various solids concentrations.

Sydney discloses a balloon catheter wherein at least a portion of the balloon and a portion of the assembly shaft is coated with a lubricious coating. Various coatings may be utilized, including silicone, polyethylene oxide and neopentyl glycol diacrylate.

None of the references, whether taken alone or in combination, discloses or even remotely suggests a water-soluble powder affixed to a polymeric/agent basecoat on an implantable medical device. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

The amendment raises no new issues and places the application in condition for allowance. Therefore, entry is proper and earnestly solicited.

Respectfully submitted,

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